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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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OLIFF & BERRIDGE, PLC
P.O. BOX 19928
ALEXANDRIA, VA 22320

[REDACTED] EXAMINER

SIEW, JEFFREY

ART UNIT	PAPER NUMBER
1637	[REDACTED]

DATE MAILED: 11 25 2002

J.S.

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/674,090	YOAV EICHEN
	Examiner	Art Unit
	Jeffrey Siew	1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 25 September 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-42 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 09 January 2002 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input checked="" type="checkbox"/> Other: <u>Wester</u> |

DETAILED ACTION

Request for Continued Examination

1. The request filed on 9/25/02 for a Request for Continued Examination (RCE) under 37 CFR 114 is acceptable. An action on the RCE follows. The response requested entry and consideration of July 25, 2002 submission. As no July 25, 2002 submission appears in the Office's records, it is believed that August 5, 2002 afterfinal amendment is being referred to. The August 5, 2002 submission has been entered and considered. Pending claims are 1-42 with claims 1,10,24,25,26,31,34,35,37 being independent claims.

Drawings

2. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 1/9/02 have been approved. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.

SPECIFICATION

3. Reference to Figures in the drawing should reflect the actual drawing figures e.g. page 29 line 20 Figure 10 is referenced but Figures 10A and 10B exist. Correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-30, 34, 38-40 & 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) The amended phrase "to **one or more** of at least two electrodes.... **onto** on the substrate" renders claims 10,24,26-28,29,30, 34 39,40,42 are grammatically confusing. It is unclear as to whether the electrode bound to the substrate. It is suggested that the claim language be amended to follow amended claim 1 format of using Roman numeral designations for the alternatives.

B) Claims 1-23 & 38 are indefinite. The claim recites a system but the added limitations appears to recite method steps of making. It is unclear as to whether the system refers to an apparatus versus a method. According to Webster dictionary 1994 edition system may refer to a structurally or anatomically group of parts or a method. As an apparatus claim, the amended language would appear more to intended use and would may still read on the prior art. The

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distinction is critical because the interpretation of the claims in light of the prior art depends on the statutory subject class.

C) In claims 10& 25 it is unclear as to the distinction between growing versus polymerization. Growing appears to refer to the added metals to nucleation centers to increase the metals in creating the bridge. It is not clear as to whether growing refers to the increase in metals or polymerization.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9,12, 17-23,35-38 & 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Mroczkowski et al (US5,284,748 Feb, 8, 1994).

Mroczkowski et al teach a method for detecting the occurrence of binding or complex forming reaction between specific substances by utilizing a binding reaction to modify an electric circuit (see whole doc. esp. abstract). They teach a diagnostic element with a biogenic substance e.g. antigen coated with onto a non-conductive base (see figure 3 part 22) between a

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pair of electrical conductors. Antibodies with gold or platinum i.e. nucleation sites are reacted with antigen to be bound (see also col. 9 line 26). The particles form aggregates of electrically conductive particles each modify the circuit. The particles are then coated with conductive substance. The device is used for assessing antibodies and antigens in blood serum of human patient (see also col. 5 line 60 to col. 6 line 12). They teach that the nucleation sites may be gold (see col.2 line 47). In Figure 1 &2 layer 23 and 24 form positive and negative terminals or electrodes (see col. 4 line 59) They test conductivity with an ohmmeter functionally connected to layers 23 & 24 of figure 1 &2. (see col. 4 line 56). They teach that channels have a width of 10 microns. Figure 8 shows a device with multiple reactions sites in columns and rows. (see col. 10 line 47-60). They also teach the reducing agent hydroquinone solution for further coating (see col. 15 line 26).They also teach detection of nucleotides (see col.1 line 21). They also teach separated assay elements in Figure 8 and the photolithographic design involving width of 3,4,5 and 7.5 um. (see col. 14 lines 21).

The response filed 9/25/02 regarding the 102 rejections of Mrocskowski has been fully considered and deemed not persuasive. He states that unlike Mrocskowski et al's device which would require recognition moieties to span the whole gap between the electrodes, the instant invention does not require the recognition moiety span the gap. While not requiring, the claims do not negatively recite that the moiety does not. The claims read that the moiety may bind to second alternative on the substrate between the electrodes. Nor do the claims recite any limitation on the number of moieties bound.

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The amended claims now recite "forming the bridge only after growing a conduction substance" would appear to recite method steps for making the apparatus system. Applicant is reminded:

**MPEP 2113 PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE
MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE
IMPLIED BY THE STEPS**

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production.

The steps of formation of the bridge would still read on the end product of Mrocskowski et al's metal colloid bridge. The response states that "the formation of complex itself or deposition or binding of nucleation center forming entities themselves not yielding a conductive bridge such bridge being formed only after growing said conductive substance" which distinguishes Mrocskowski et al which involves the binding of antigen to the surface and the binding of antibody with colloid to grow the bridge (see Figure 2d and 2E and 4A & 4B). First, referring to **MPEP 2113** the language recites the method of production which does not distinguish from Mrocskowski et al's end apparatus product with a bridge that grows from the continual binding of the antibody to reach the other side of the electrode (see figure 4B).

Moreover, MPEP 2113 further states

**ONCE A PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS
FOUND AND A 35 U.S.C. 102 /103 REJECTION MADE, THE BURDEN
SHIFTS TO THE APPLICANT TO SHOW AN UNOBlVIOUS DIFFERENCE**

The 102 and the following 103 rejections over apparatus claims over the primary reference Mrocskowski et al are therefore maintained.

Moreover regarding the 103 rejections over Mrocskowski et al and Hisada et al, the applicant argues that Hisada et al is nonanalogous art and directed toward large output problems. This is found convincing. However, the structural limitations of such integrated device appears to be met by Mrocskowski et al alone. The claims recite the alternative of diode or non-linear component permitting flow in only one direction from first conductor to second conductor. Figure 8 shows an N x N junctions of positive and negative conductors such that current flow would be unidirectional (see col.4 lines 55-60).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mrocskowski et al (US5,284,748 Feb. 8, 1994) in view of JP 04-148669 May 21 1992.

The teachings of Mrocskowski et al are described previously.

Mrocskowski et al do not teach DNA.

JP 04-148669 teach a molecule securing device in which a chain is formed by using two aluminum electrodes installed on a substrate (see whole document). Between electrode 1 & 2 an electrical field is charged via leads 3 and 4 (see page 4 and Figs. 1 & 2). The device is applied to DNA molecules (see page 2).

One of ordinary skill in the art would have been motivated to apply teachings of DNA binding to Mrocskowski et al's device in order to detect DNA interactions. As it was well known in the art to detect DNA for disease mutations and as JP-04-148669 teach the successful use of DNA binding to provide a conducting connection between electrodes, it would have prima facie obvious to bind DNA in order to detect target DNA.

As stated previously, per MPEP 2113 the product claims would still read on Mrocskowski et al. As Mrocskowski et al teach that targets may be nucleotides, it would have been prima facie obvious to apply teachings of JP 04-148669 that DNA as a base layer to connect electrodes as in Mrocskowski et al's antigen in order to detect target nucleic acids.

6. Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mrocskowski et al (US5,284,748 Feb. 8, 1994) .

The teachings of Mrocskowski et al are described previously.

Mrocskowski et al do not teach explicitly a kit.

Mrocskowski et al's reagents into a kit in order to allow the practitioner easy access to all the reagents to perform the assay. It was well known and commonly practiced in the art to incorporate reagents into kits. It would have been prima facie obvious to put Mrocskowski et al's reagents into a kit so that one would be able to have the reagents to construct and perform the diagnostic assay efficiently.

The response states that instant invention requires only a single complex between recognition moiety and target Mrocskowski however requires formation of aggregates and the claims explicitly recite it does not require formation of aggregates. The response is reminded that the kit claims read on components not on their intended use. The method of using kit claims for the present invention may well differ from the Mrocskowski et al's method but the Mrocskowski et al's colloid, metal and hydroquinone reagents are not distinguished. The amended language merely recites intended use of the reagents. Moreover response states the teaching "one may be able to design a kit but Mrocskowski would not have lend one to make use for the method of the instant invention" (see page 14 response filed 9/25/02). Herein lies the essence of the interpretation of kit claims. Although the use of reagents may differ, the reagents in the kit are identical. The rejection is maintained.

SUMMARY

7. Claims 10,11,24,25,26-30,34, 39,40 & 42 are free of the prior art but rejected under 112 second paragraph. There is no prior art that teach or suggest the claimed method of forming complex not from the formation of complex between recognition moiety and target or deposition or binding of nucleation center forming entities but only after growing conductive metal substance. Nor is there prior art that teach or suggest claimed method using monomers and polymerizing.

CONCLUSION

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

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Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and Before Final FAX (703) 872-9306 or After Final FAX (703) 30872-9307.

Jeffrey Siew
JEFFREY SIEW
PRIMARY EXAMINER

November 23, 2002